IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: ZOLOFT (SERTRALINE HYDROCHLORIDE) PRODUCTS LIABILITY LITIGATION	**MDL NO. 2342** **12-MD-2342** **HON. CYNTHIA M. RUFE**
THIS DOCUMENT RELATES TO ALL ACTIONS	

SPECIAL DISCOVERY MASTER'S REPORT AND RECOMMENDATION NO. 10
(REGARDING THE PSC's REQUEST THAT PFIZER PROVIDE MORE COMPLETE INFORMATION IN DEFENDANTS' FACT SHEETS)

March 28, 2014

I. INTRODUCTION AND BACKGROUND

The PSC states that Pfizer has not provided complete information in its responses to Defendants' Fact Sheets. The Defendants' Fact Sheet ("DFS") is a list of information and documents that Pfizer agreed to provide with respect to each plaintiff whose case is in the Initial Discovery Pool. The parties arrived at the content of the Defendants' Fact Sheet following negotiations. During those negotiations, the PSC agreed to give up the opportunity to take certain depositions in the Initial Discovery Pool cases in exchange for Pfizer's agreement to include certain categories of information in the Defendants' Fact Sheet.

This is the PSC's second request for relief aimed at getting the information that is at issue. In Report and Recommendation No. 7, dated February 20, 2014 and approved by the Court in Pretrial Order No. 53 on March18, 2014, I dealt with a request by the PSC that Pfizer be ordered to respond to certain document request that plaintiffs had served. I recommended that the request be denied. I recommended that Pfizer should not be required to respond to document requests to the extent that the document requests called for information beyond the scope of the

Defendants' Fact Sheets. To the extent that the document requests called for information already covered by the Defendants' Fact Sheets, I recommended Pfizer not be required to respond to the document requests because the document requests were duplicative of the requests in the Defendants' Fact Sheets. I did not deal with the question of whether Pfizer had responded fully to the Defendants' Fact Sheets, as the question had not been presented.

The PSC now seeks an order compelling Pfizer to respond more completely to the Defendants' Fact Sheets.

II. THE PSC'S THREE CATEGORIES OF REQUESTS AND THE DEFENDANTS' FACT SHEETS

The PSC's submission that is now before the court, dated March 4, 2014, identifies three categories of information that the PSC seeks:

1. "Information Pfizer has specific to Plaintiffs' doctors' prescribing practices, network of physicians, and how Pfizer targeted Plaintiffs' doctors for promotion of Zoloft (which usually comes from the Marketing Department)."

2. "Internal documents referencing inquiries by Plaintiffs' doctors related to Zoloft's safety or efficacy including off-label uses (which are handled through the Medical Information Department and medical liaisons) and the medical liaisons involvement with Plaintiffs' doctors at meetings, educational programs or events."

3. "The internal communications (including emails) about Plaintiffs' doctors, and any email communications with Plaintiffs' doctors (which could come from any of these Departments [i.e., Marketing, Medical Information, or Sales], all of which are involved in the 'Cross Functional Team' responsible for Zoloft)."

PSC letter submission of March 4, 2014, page 2.

Primarily, this resolution of the PSC's request turns on whether the items discussed above actually fall within the scope of what is called for by the Defendants' Fact Sheets.

Section II of the Defendants' Fact Sheet describes the information that Pfizer must give relating to contacts and communications with individual plaintiffs' treating physicians. Sections II .A and II.B of the Defendants' Fact Sheets call for production of various types of communications with a plaintiffs' treating physician "concerning Zoloft" (Exhibit A, page 3, ¶ II.A) or "related to Zoloft." (Exhibit A, page 3, ¶ II.B) Pfizer is also required to identify and produce provide the documents that are responses to those communications. (Exhibit A, page 3, ¶ II.B)

Section II.C of the Defendants' Fact Sheet calls for disclosure of the names of various representatives who "came in contact with the treating physician in connection with Zoloft during the timeframe for which such records are available." (Exhibit A, page 4, paragraph II.C) The representatives whose contacts are to be described need not, as is stated in the Fact Sheet, only be sales representatives. They may be medical liaisons, marketing organization representatives or "any other detail person." (Id.) These individuals are to be identified, the timeframes of their contacts are to be specified, and all "call notes" for any contact by any representative of Pfizer with any treating physician are to be produced if they relate either to (1) Zoloft; or (2) "any other antidepressant and potential risks associated with maternal use in pregnancy or birth defects in children. . . ." (Id.)

The Fact Sheet limits Pfizer's duty to search for and produce these documents in connection with its answers to the Fact Sheet. It applies standards of reasonableness and reasonable accesibility in what is required of Pfizer::

> Defendants will provide as much information as they can based on searches of reasonably accessible information and will supplement their responses if they learn that they are incomplete or incorrect in any material respect. . . . Defendants shall make their best effort to produce the documents . . . to the extent they are reasonably available, with the completed DFS. If Defendants are not able to

> produce certain documents requested herein with the completed DFS, they shall so advice in the DFS and shall provide an estimated date for producing any such documents.

Defendants' Fact Sheet, Preamble. Similarly, the Certification to the Fact Sheet calls for a statement that Pfizer's responses are based on "reasonably accessible information."

III. RESOLUTION

The first category of information sought by the PSC, as outlined above, is not within the scope of the DFS. When the PSC asks for information Pfizer has that is "specific" to a treating physician's "prescribing practices," information about a treating physician's network, or information about how Pfizer targeted that treating physician for promotion of Zoloft, it is going beyond what is called for in Section II of the Defendants' Fact Sheets. What PSC is seeking is Pfizer's internal communications *about* the doctors, not records of communications *with* the doctors.

In its previous motion, the PSC described why the information *about* the treating physicians is important. It may be helpful in the selection of cases, and it may be even more helpful in developing proof about Pfizer's marketing methods, which the PSC has argued is relevant under the law of at least some states. But it is not what was agreed upon as the DFS was negotiated, and discovery of this material in a later phase is not foreclosed.

The second category of information or documents that the PSC calls for in its recent request for relief is for:

> Internal documents referencing inquiries by Plaintiffs' doctors related to Zoloft's safety or efficacy including off-label uses (which are handled through the Medical Information Department and medical liaisons) and the medical liaisons involvement with Plaintiffs' doctors at meetings, educational programs or events.

A document that describes a medical liaison's contact with a treating physician may be considered a call note within the meaning of Section II.C of the DFS. The term "call note" is not defined in the Fact Sheet or in any Pretrial Order discussing the Fact Sheets. The term appears to be a term of art in the field of pharmaceutical marketing and pharmaceutical company relations with physicians. It is not defined in any business dictionary that I could find, and neither party pointed to any business dictionary definition. A sensible definition of it would include any notation in Pfizer's files about any contact with a physician.

There is no reason to construe the term as limited to notes made by sales representatives when the Fact Sheet refers to people other than sales representatives. While Pfizer states that the sales representative notes are the only notes that are "reasonably accessible," Pfizer has not substantiated this statement with any affidavit or other submission that describes how it might be burdensome. However much the Defendants' Fact Sheet limits production of information and documents to what is "reasonably accessible," it is not up to Pfizer to unilaterally decide what is reasonably accessible or available without providing proof of burdensomeness. Generally, it is up to a party who claims that production is burdensome to prove that it is so. In addition, the preamble's discussion of reasonableness is a temporal one. If a sales representative's notes are what are only reasonably available on the first pass at production, the preamble calls for Pfizer to state when other notes made by other personnel will be available upon further search. Pfizer may postpone the production of call notes made by people other than sales representatives, but it must still make the production.

Also within the second category of what the PSC seeks are "documents referencing inquiries by Plaintiffs' doctors related to Zoloft's safety or efficacy including off-label uses (which are handled through the Medical Information Department and medical liaisons)." To the

degree that such documents describe communications with a plaintiff's treating physicians, those documents may be considered call notes, and they should be produced, for the reasons described above.

The requirement of production of these call notes applies only to notes about discussions of Zoloft or other anti-depressants, as is stated in Section II.C of the Fact Sheets. If a Pfizer representative had a contact at a meeting or event and there was no discussion of Zoloft or of the efficacy or safety of another antidepressant, then it does not fall within the scope of Section II.C of the DFS.

The third category of what the PSC requests is internal communications *about* the treating physicians and emails between those doctors and anyone in Pfizer's marketing, sales, or medical information departments. Some of this is called for in the Defendants' Fact Sheets. Internal communications *about* physicians are, as discussed above, not the same as communications *with* physicians, and they are not called for by the Defendants' Fact Sheets. However, when those internal communications themselves discuss communications with physicians relating to Zoloft or other antidepressants, then they fall within section II of the Defendants' Fact Sheets as call notes. They describe a communication with a physician on the topics described in the Fact Sheets, and they are to be produced. Emails to and from the doctors from *any* department of Pfizer where the communication was about Zoloft or its safety or efficacy are called for by the Defendants' Fact Sheets. Internal discussions within Pfizer that discuss or describe contacts with doctors on these topics are also called for by the Defendants' Fact Sheets. However, *all* emails between Pfizer and the treating physician are not called for by the Defendants' Fact Sheets.

IV. SUMMARY

I recommend that Pfizer's request be granted in part and denied in part. Documents about communications with a plaintiffs' treating physician that relate to Zoloft or to the efficacy or safety of any other antidepressant are call notes that fall within the scope of the Defendants' Fact Sheets, no matter whether those documents were written by a sales representative or by another Pfizer representative. Documents about those doctors that do not evidence or describe such communications are not within the scope of the Defendants' Fact Sheet, and need not be produced at this time. This does not preclude efforts to obtain such documents as part of discovery that is to be taken during a later phase of the litigation.

3/28/14

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IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: ZOLOFT (SERTRALINE HYDROCHLORIDE) PRODUCTS LIABILITY LITIGATION	:	**MDL NO. 2342** **12-MD-2342**
	:	**HON. CYNTHIA M. RUFE**
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SPECIAL DISCOVERY MASTER'S REPORT AND RECOMMENDATION NO. 10
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Exhibit "A"

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: ZOLOFT (SERTRALINE HYDROCHLORIDE) PRODUCTS LIABILITY LITIGATION	:	**MDL NO. 2342** **2:12-md-02342-CMR** **HON. CYNTHIA M. RUFE**
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DEFENDANTS' FACT SHEET

For each Plaintiff in the Initial Discovery Group from whom a substantially completed Plaintiff Comprehensive Fact Sheet ("PFS") has been received, Defendant Pfizer Inc. and, where applicable, Defendant Greenstone LLC ("DEFENDANTS") will complete this Defendant Fact Sheet ("DFS") and identify or provide documents and/or information responsive to the questions set forth below to the best of their knowledge. Defendants will provide as much information as they can based on searches of reasonably accessible information and will supplement their responses if they learn that they are incomplete or incorrect in any material respect, including in the event that additional information is provided from Plaintiffs that relates to the questions raised in the DFS. The DFS shall be completed in accordance with the requirements and guidelines set forth in the applicable Pretrial Orders.

Defendants will attach additional sheets of paper if necessary and will identify any documents they are producing as responsive to a question or request by bates number.

Defendants will serve a completed DFS on Plaintiff's primary counsel as identified in the PFS 45 days after a substantially completed PFS has been served on Defendants. Defendants shall make their best effort to produce the documents requested herein, to the extent they are reasonably accessible, with the completed DFS. If Defendants are not able to produce certain documents requested herein with the completed DFS, they shall so advise in the DFS and shall provide an estimated date for producing any such documents.

DEFINITIONS

As used herein, "YOU," "YOUR," or "YOURS" means the responding Defendants.

"DEFENDANTS" shall refer to Pfizer, Inc. f/k/a PFIZER, including its former division Roerig; and, where it is named in Plaintiffs' Complaint, Greenstone, LLC, f/k/a GREENSTONE.

As used herein, the phrase "TREATING HEALTHCARE PROVIDER" means: (1) any physician or other individual medical provider identified by full name and address in the PFS who prescribed and/or dispensed Zoloft® to the Plaintiff during her pregnancy with the Minor Plaintiff; and/or (2) any physician specializing in obstetrics or gynecology who is identified by full name and address in the PFS and treated Plaintiff during her pregnancy with the Minor Plaintiff.

As used herein, the term "DOCUMENT" shall, consistent with Federal Rule of Civil Procedure 34(a)(1)(A) refer to any "designated documents or electronically stored information—including writings, drawings, graphs, charts, photographs, sound recordings, images, and other data or data compilations—stored in any medium from which information can be obtained either directly or, if necessary, after translation by the responding party into a reasonably usable form."

I. CASE INFORMATION

This DFS pertains to the following case:

Case caption: _____

Civil Action No.: _____

Court in which action was originally filed: _____

Date this DFS was completed: _____

II. CONTACTS WITH TREATING HEALTHCARE PROVIDERS

For each Treating Healthcare Provider identified in the PFS, please provide the following:

A. Dear Doctor Letters: For each "Dear Doctor," "Dear Healthcare Provider," "Dear Colleague," or other similar type of document or letter sent to the Treating Healthcare Provider concerning Zoloft, please:

1. Identify the master letter sent, including bates number.

2. State the date the master letter was sent to the Treating Healthcare Provider, and provide the name and address to whom the letter was sent.

Response:

Date Letter Sent	Bates Number of Master Letter	Recipient (Name and Address)

B. Physician's Information Request Letters ("PIR"): If the Treating Healthcare Provider has ever initiated a PIR or any other similar information request related to Zoloft, please produce any request and:

1. Identify the date of the request and the recipient.
2. Provide the name and address of the sender or requestor.
3. Provide the bates number of the request.
4. State whether or not a response to the PIR was sent or provided.

Response:

Date of Request	Recipient (Name and Address)	Sender (Name and Address)	Bates Number of Request	Response? (Yes/No)

In addition, for each PIR or similar information request to which a response was sent as indicated by a "Yes" above, please produce any response and:

1. Identify the format of the response.
2. Identify the date the response was sent or provided.
3. Provide the name and address of the sender of the response.
4. Provide the name and address of the recipient of the response.
5. Provide the bates number of the response.

Response:

Format of Response	Date Sent	Sender (Name and Address)	Recipient (Name and Address)	Bates Number of Response

C. Other Contacts: For each Treating Healthcare Provider, please:

1. Identify by name any of the Defendants' Sales Representatives, Marketing Organization Representatives, medical liaisons, and/or any other detail person ("Representative") who came in contact with the Treating Healthcare Provider in connection with Zoloft during the timeframe for which such records are available.

2. Identify the time period during which the Representative had contact with the Treating Healthcare Provider.

3. Produce complete "call" notes for each such contact that relates to: (1) Zoloft; and/or (2) any other antidepressant medication and potential risks associated with maternal use in pregnancy or birth defects in children born to mothers who used antidepressants while pregnant.

Response:

Healthcare Provider	Name of Representative	Date(s) of Contact	Current or Former Employee	Specialized Training?

D. Samples: If Defendants or their Representatives ever provided any Treating Healthcare Provider with Zoloft samples, please provide the following to the extent reasonably accessible:

1. Identify the Treating Healthcare Provider who received the samples.

2. Identify the date on which such samples were provided.

3. Identify the amount, dosage, and lot numbers of such samples.

4. Identify the name of the Representative who provided the samples.

Response:

Healthcare Provider	Date Shipped/Provided	Amount, Dosage, and Lot Numbers	Representative who Provided

III. CONSULTING WITH PLAINTIFF'S TREATING HEALTHCARE PROVIDER

For each Treating Healthcare Provider identified in the PFS, please state the following:

A. Consulting and Professional Relationships: If the Treating Healthcare Provider has been consulted, retained, or compensated by either Defendant as a "key opinion leader," "thought leader," member of a "speaker's bureau," "clinical investigator," "consultant," or in a similar capacity or otherwise has or had a financial relationship with either Defendant, please:

1. Identify the Treating Healthcare Provider.

2. Identify the date(s) that the Treating Healthcare Provider was consulted, retained, or compensated.

3. State the nature of the affiliation.

4. State the amount of money paid to the Treating Healthcare Provider, if available.

Response:

Treating Healthcare Provider	Date(s) Consulted, Retained, or Compensated	Nature of Affiliation	Remuneration

B. For any Treating Healthcare Provider identified in response to III.A., please identify and produce all documents or correspondence provided to the Treating Healthcare Provider by Pfizer or Greenstone concerning the potential benefits and/or risks of antidepressant medications (including Zoloft) and/or the treatment of psychological and/or psychiatric disorders, maternal fetal medicine and/or obstetrics and gynecology, or neonatology.

Response:

_____

_____

C. For each Treating Healthcare Provider identified in Section III.A., please identify and produce all consulting agreement contracts and/or retainer agreement contracts entered into with the Treating Healthcare Provider.

Response:

_____

_____

IV. PLAINTIFF'S TREATING HEALTHCARE PROVIDERS' PRACTICES

For each Treating Healthcare Provider identified in the PFS, please state whether you have in your possession prescriber-level information concerning the physician's prescribing of Zoloft or sertraline?

Yes _____ No _____

If "Yes," please produce such information.

Response:

_____

_____

V. PLAINTIFF'S MEDICAL CONDITION

A. To your knowledge, have you been contacted by Plaintiff, any of his/her Treating Healthcare Providers, or anyone acting on behalf of Plaintiff (other than Plaintiff's counsel) concerning Plaintiff, other than in connection with the present lawsuit?

Yes _____ No _____

B. If you have been contacted by any person or entity concerning the Plaintiff, please state the name of the person(s) who contacted you and the name and address of the person(s) who responded.

Response:

_____

_____

C. Please identify all non-privileged documents that reflect any communication between any person identified in Section V.A. or V.B. above and you concerning Plaintiff.

Response:

_____

_____

D. Please produce a copy of any Adverse Event Report or MedWatch form that refers or relates to Plaintiff, as well as any underlying documentation (e.g., the adverse event source file, medical records, and non-privileged investigative reports) that refers or relates to Plaintiff.

Response:

_____

_____

_____

CERTIFICATION

I declare under penalty of perjury that the information provided in this Defendants' Fact Sheet is true and correct to the best of my knowledge and belief and the same provides all reasonably accessible responsive information and documents unless otherwise specified above.

_____	_____	_____
Signature	Print Name	Date